PTO/SB/21 (02-04) (AW 02/2004)
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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission 5 pgs & 6 refers

| Application Number   | 10/679,913                |   |
|----------------------|---------------------------|---|
| Filing Date          | October 6, 2003           |   |
| First Named Inventor | James Ronald Lawter       |   |
| Art Unit             | Unknown                   |   |
| Examiner Name        | Not Yet Assigned          |   |
| Attorney Docket No.  | ORA5005USANP (J&JO-105US) | • |

| E  | NCLOSURES (Check all that apply)  |      |  |  |
|--|---|------|--|--|
| Fee Transmittal Form Fee Attached  | ☐ Drawing(s) ☐ Licensing-related Papers   |      | After Allowance Communication to Group   |  |
| Amendment/Reply After Final Affidavits/Declaration(s)  Extension of Time Request Express Abandonment Request  Information Disclosure Statement Certified Copy of Priority Document(s)  | Petition  Petition to Convert to a Provisional Application  Power of Attorney, Revocation, Change of Correspondence Address  Terminal Disclaimer  Request for Refund  CD, Number of CD(s) |      | Appeal Communication to Board of Appeals and Interferences  Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  Proprietary Information  Status Letter  Other Enclosure(s) (please identify below): 6 references; Post Card |  |
| Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53  | Remarks:  |      |  |  |
| SIGNATURE  | OF APPLICANT, ATTORNEY OR AG  | ENT  |  |  |
| Firm or Individual Name Signature  Robert L. Anderson Registration No. (Attorney/Agent)  Registration No. (Attorney/Agent)  25,771   |   |      |  |  |
| Date March 5, 2004   |   |      |  |  |
| CERTIFICATE OF TRANSMISSION / MAILING  |   |      |  |  |
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| "Typed or printed name Patricia C. Boccella  | 0   |      |  |  |
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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:

10,679,913

Applicant: Filed:

James Ronald Lawter Öctober 6, 2003

Title:

MUCOADHESIVE TETRACYCLINE FORMULATIONS

TC/A.U.: Examiner:

Unknown Unknown

## **INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO 1449 (RP) submitted herewith. A copy of each of the listed references is also enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed within three months of the filing date of the above-referenced application or before mailing of the first Official Action. No first Official Action has yet been received and it is presumed that none has yet been mailed. No fee or statement is required. 37 C.F.R. § 1.97(b).

Respectfully submitted,

Robert L. Andersen, Reg. No. 25,771

Attorney for Applicant

RLA/pb

Enclosures: PTO Form 1449

(6) References Transmittal Form

Dated: March 5, 2004

P.O. Box 980Valley Forge, PA 19482(610) 407-0700

P.O. Box 1596
Wilmington, DE 19899
(302) 778-2500

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|---|---------------------|---------------------------|--|
|   | Application Number  | 10/679,913                |  |
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br>(Use as many sheets as necessary) | Filing Date         | October 6, 2003           |  |
|   | First Named         | James Ronald Lawter       |  |
|   | Art Unit            | Unknown                   |  |
|   | Examiner Name       | Unknown                   |  |
| SHEET 1 of 2  | Attornov Docket No. | OBA5005USAND(18 IO-105US) |  |

|                       | U.S. PATENT DOCUMENTS |  |                                  |  |   |  |  |
|-----------------------|-----------------------|--|----------------------------------|--|---|--|--|
|                       |                       | Document Number                            |                                  |  | Pages, Columns, Lines, Where                    |  |  |
| Examiner<br>Initials* | Cite<br>No.1          | Number - Kind Code <sup>2 (if known)</sup> | Publication Date<br>(MM-DD-YYYY) | Name of Patentee or<br>Applicant of Cited Document | Relevant Passages or Relevant<br>Figures Appear |  |  |
|                       |                       | US-6,025,326                               | 02-15-2000                       | Steinberg et al.                                   |   |  |  |
|                       |                       | US-  |                                  |  |   |  |  |
|                       |                       | US-  |                                  |  |   |  |  |
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|                       |              | FOREIGN PA  | TENT DOCUMEN                     | TS                          |  |                |
|-----------------------|--------------|---|----------------------------------|-----------------------------|--|----------------|
| _                     |              | Foreign Patent Document   | D. hii D-t                       | Name of Patentee or         | Pages, Columns,<br>Lines, Where Relevant<br>Passages or Relevant |                |
| Examiner<br>Initials* | Cite<br>No.1 | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5 (If known)</sup> | Publication Date<br>(MM-DD-YYYY) | Applicant of Cited Document | Figures Appear   | T <sup>6</sup> |
|                       |              | WO 99/45910   | 09-16-1999                       | Sonis et al.                |  |                |
|                       |              | WO 01/19362   | 03-22-2001                       | Lawter et al.               |  |                |
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| Examiner  |   | Date       |  |
|-----------|---|------------|--|
| Signature | • | Considered |  |
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<sup>2</sup>See Kind Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04.
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For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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| Substitute for Form                                      |                      | Complete if Known        |          |
|--|----------------------|--------------------------|----------|
|  | Application Number   | 10,679,913               |          |
| INFORMATION DISCLOSURE                                   | Filing Date          | October 6, 2003          | _        |
| STATEMENT BY APPLICANT (Use as many sheets as necessary) | First Named Inventor | James Ronald Lawter      |          |
|  | Art Unit             | Unknown                  | <u> </u> |
|  | Examiner Name        | Unknown                  |          |
| SHEET 2 of 2   | Attorney Docket No.  | ORA5005USANP(J&JO-105US) |          |

|                       |              | NON-PATENT LITERATURE DOCUMENTS  |    |
|-----------------------|--------------|--|----|
| Examiner<br>Initials* | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T² |
|                       | 1.           | SONIS, S.T., "Oral Complications of Cancer Therapy," Cancer Principles & Practice of Oncology 4 <sup>th</sup> Ed., Volume 2, 1993, Pages 2385-2394, J.B. Lippincott Company, Philadelphia.   |    |
|                       | 2.           | ROTHWELL et al., "Palliation of Radiation-Related Mucositis" J. Am. Accoc. Of Hospital Dentists, Special Care in Dentistry; September to October, 1990, 10(1), pages 21-25   |    |
| :                     | 3.           | SONIS, S.T., "Oral Complications." <i>Cancer Medicine</i> , Pages 2381-2388, 1993, Holland et al. Eds, Lea & Febiger, Philadelphia   |    |
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